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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Robert Peter Klein, et al.
Serial No.	:	09/720,287 (Conf. No.: 1252)
Filed	:	May 10, 2001
Title	:	Transdermal Therapeutic System Containing Hormones and Crystallization Inhibitors
Examiner	:	Isis Ghali
Art Unit	:	1615
Attorney Docket	:	RO0208US (#90568)

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CLEAN CLAIMS

1. (Twice amended) A transdermal therapeutic system in plaster form for controlled release of oestradiol in combination with norethisterone acetate, comprising:

a backing layer; and

a reservoir supersaturated with active ingredients and containing oestradiol and norethisterone acetate, said reservoir is attached to said backing layer and is prepared using polyacrylate pressure-sensitive adhesives and crystallization inhibitors; and is a detachable protective layer, wherein the crystallization inhibitor is an amino group -containing polymer selected from the group consisting of polyaminoamides,

polyaminoimidazolines, polyetherurethaneamines, polyamines, polyglucosamines and a copolymer based on butyl methacrylate, 2-dimethylaminoethyl methacrylate and methyl methacrylate being present in a molar ratio of 1:2:1 (butyl methacrylate : 2-dimethylaminoethyl methacrylate : methyl methacrylate).

3. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir comprises at least one crystallization inhibitor in proportion of from 0.05 to 30% by weight.

4. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir comprises oestradiol and norethisterone acetate in a weight ratio of from 1:2 to 1:15, and in an overall concentration of up to 25% by weight.

5. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir includes a constituent from the group consisting of aging inhibitors, plasticizers, antioxidants and absorption improvers, the plasticizers being used in a concentration of 0 to 5% by weight and the aging inhibitor in a concentration of 0.1 to 2% by weight.

6. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the pressure-sensitive adhesive is selected from the group consisting of a solvent-based adhesive, a dispersion adhesive, a hot-melt adhesive and a UV-crosslinkable adhesive.

7. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir consists of at least two layers.

8. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir has a layer thickness of 0.02 mm to 0.500 mm.

9. (Twice amended) A transdermal therapeutic system according to claim 1, wherein the reservoir is provided with an additional pressure-sensitive adhesive layer.

11. (Amended) A transdermal therapeutic system according to claim 4, wherein the reservoir comprises oestradiol and norethisterone acetate in a weight ratio of from 1:3 to 1:7.

12. (Amended) A transdermal therapeutic system according to claim 8, wherein the reservoir has a layer thickness of 0.030 to 0.200 mm.

13. (Amended) A transdermal therapeutic system according to claim 9, wherein the reservoir is provided with a pressure-sensitive adhesive margin.

14. (Amended) A transdermal therapeutic system according to claim 1, wherein the reservoir is provided with a pressure-sensitive adhesive margin.

15. (Amended) A method for providing a transdermal therapeutic system for therapeutic applications in human medicine, said method comprising:

applying said transdermal therapeutic system to the skin of a patient by applying a polyacrylate pressure-sensitive adhesive to said transdermal therapeutic system; and

controlling the release of oestradiol in combination with norethisterone acetate to the human skin by providing a reservoir in said transdermal therapeutic system, said reservoir being supersaturated with active ingredients and being attached to a backing layer, wherein said reservoir comprises at least one amino group-containing polymer and at least one adhesive selected from the group consisting of a polyacrylate pressure-sensitive adhesive layer and a pressure-sensitive adhesive margin.

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